NEUROSURGERY INC.

A Division Of Physicians Care Of Va., PC.

DARWIN J. FERRY, JR. M.D. (Retired)

JOHN A. FELDENZER, M.D., F.A.C.S. RALPH O. DUNKER, JR., M.D. SANDER W. LEIVY, M.D.

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November 30, 1999

Document Management Branch (HFA-305) Food and Drug Administration 5630 Fishers Lane, Room 1061 Rockville, Maryland 20852

Re: Docket No. 97N-484S

To Whom It May Concern:

I am a neurosurgeon in Roanoke, Virginia who is quite concerned over the recent FDA proposal to regulate allograft tissue as a medical device. Allograft bone has been used for years to help with bone fusion by different medical specialties. I believe it would be wrong to regulate this as an actual medical device, as this could limit its use; this being an important adjunct to obtain bone fusion in our patients.

I thank you for your consideration in this matter.

Sincerely,

Sander W. Leivy, M.D.

SWL/lt

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JOHN A. FELDENZER, M.D., F.A.C.S. RALPH O. DUNKER, JR., M.D. SANDER W. LEIW, M.D.

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